

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### The comparison of the effect of music on self-efficacy and the severity of violence expressed in women under domestic violence with control group

#### Protocol summary

##### Study aim

Determining the effect of music on the self-efficacy and the severity of violence expressed of women under domestic violence

##### Design

The number of samples determined in each group is 57 people, considering the 10% drop, the number of samples in each group should be considered 63 people. Random allocator software will be used for random allocation.

##### Settings and conduct

Sampling in health centers and family physician bases in Sari and intervention at home and virtual.

##### Participants/Inclusion and exclusion criteria

The study population includes women who are married, have at least one year of experience living with their sexual partner, and are subjected to any form of sexual violence that causes (or is likely to cause) physical, sexual, or psychological harm to women. It is very painful for them or leads to forced deprivation of individual or social liberty, as well as being literate and willing to participate in the study.

##### Intervention groups

In the intervention group, first, a list of non-verbal music with the necessary characteristics to create relaxation is prepared with the opinion of a music expert and is presented to the participants of this group. After the participant selects their favorite music, they will receive 7 sessions of 45-minute (2 sessions per week) individually according to the Covid-19 pandemic conditions at home. Phone calls will be made twice a week and the researcher will monitor the intervention and homework. The interventions will be performed by a master's degree student in midwifery counseling under the direct supervision of a research team consisting of a reproductive health specialist, a doctorate in nursing, and a master's degree in music.

##### Main outcome variables

Self-efficacy; severity of expressed violence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161126031117N10**

Registration date: **2021-08-31, 1400/06/09**

Registration timing: **prospective**

Last update: **2021-08-31, 1400/06/09**

Update count: **0**

##### Registration date

2021-08-31, 1400/06/09

##### Registrant information

##### Name

Soghra Khani

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 8918

##### Email address

s.khani@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-16, 1400/07/24

##### Expected recruitment end date

2022-01-13, 1400/10/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The comparison of the effect of music on self-efficacy and the severity of violence expressed in women under domestic violence with control group

## Public title

Music on self-efficacy and severity of expressed violence of women under domestic violence

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Married middle-aged and young women with experience of living with their husbands for at least a year and under domestic violence (according to the Parsa system) Be able to read and write. Have no habit of listening to music No pregnancy No chronic psychiatric disorders And major at the time of the study No history of schizophrenia and bipolar disorder No substance abuse No participation in psychological intervention sessions related to domestic violence in the last 6 months No use of antipsychotic drugs, antidepressants or mood stabilizers in Time of the study No history of suicide attempt, No history of hospitalization in the psychiatric ward (based on self-declaration) Consent of the wife and her husband to participate in the study.

### Exclusion criteria:

The patient's desire to leave the study Occurrence of significant stressful events during the study (loss of a family member, job loss, bankruptcy, etc.)

## Age

To **54 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **126**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In order to randomly assign, use Random allocator software and (according to the number of 126 samples) two groups of numbers will be obtained randomly. Individuals will then be placed in intervention or control groups. For example, the numbers in group A will be women receiving the intervention and group B will be in control. Then, by referring to each of the women, we look at the table of numbers in which group they are and according to the table, they will be in the intervention or control group. This will be done for all participants. For example, the number one is in group B, which means that the first client is in the control group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Research participants and staff of health centers. While

explaining the work, we only ask the health staff of the centers to provide us with the contact numbers of women who have been abused if these women agree, and we do not explicitly say, for example, that Ms. X is going to be in the control group or to intervene. We will explain the work process in general. Outcomes will be assessed by health centers' midwife that will not aware of participants' group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

##### Street address

Vicce chancellor for research of Mazandaran University of Medical Sciences, Moalem square

##### City

sari

##### Province

Mazandaran

##### Postal code

48178-57344

#### Approval date

2021-06-22, 1400/04/01

#### Ethics committee reference number

IR.MAZUMS.REC.1400.272

## Health conditions studied

### 1

#### Description of health condition studied

Women under domestic violence

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Self-efficacy

#### Timepoint

At the time of enrollment - immediately after the intervention and one month after the intervention

#### Method of measurement

Schwartz and Jurosaem General Self-Efficacy Questionnaire ( General Self- Efficacy Scale)

## Secondary outcomes

### 1

#### Description

The severity of the violence expressed

#### Timepoint

At the time of enrollment - immediately after the intervention and one month after the intervention

#### Method of measurement

Domestic Violence Questionnaire against Women  
Mohseni Tabrizi et al

## Intervention groups

### 1

#### Description

In the intervention group, they will receive 7 sessions of 45 minutes (2 sessions per week) individually according to the coronary pandemic conditions at home. Phone calls will be made twice a week and the researcher will monitor the intervention and homework. The interventions will be performed by a counseling master student in midwifery, under the direct supervision of a research team consisting of a reproductive health specialist, a doctoral nurse, and a music master. In this study, the meaning of music is non-verbal songs with the sound of nature such as wind and the sound of the sea wave and piano pieces that are uplifting and refreshing. Invigorating themes (rhythmic) rhythmic pieces with a relatively sharp melody that inspires vitality and vitality away from excitement and impatience and is accompanied by stability and calmness, which is used by Standley music therapy through Mp3 player in each The meeting will be broadcast. In the first session, a folder containing non-verbal music will be played to the participant and based on their choice, it will be used until the end of the intervention. It should be noted that all non-verbal songs in the file will have the same theme and rhythm. In this study, the first, second and third methods of stand-up music therapy will be used for the intervention group. Passive music is a joy to listen to non-verbal pieces. A special melody to create joy in patients should have a refreshing musical theme. Invigorating themes (rhythmic) rhythmic pieces with a relatively sharp melody that induces vitality and vivacity away from excitement and impatience and is accompanied by stability and calm. Active Musical Activities in Music Therapy Sessions This study will include a discussion of musical emotions, singing, and speaking along with the piano.

#### Category

Treatment - Other

### 2

#### Description

Control group: Routine care

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sari health centers and Sari family doctors base

##### Full name of responsible person

Dr Aghil Barzegar

##### Street address

Amir Mazandarani St. - Kargar Square - Sari Health Center

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##### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr akbar hedayatzade omran

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#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Mazandaran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr Soghra Khani  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**  
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s.khani@mazums.ac.ir  
**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Research-related information is shared with the aim of keeping individuals' names and identities confidential and adhering to the 31 Code of Ethics.

### When the data will become available and for how long

2022

### To whom data/document is available

All researchers and research enthusiasts

### Under which criteria data/document could be used

For review and supplementary research

### From where data/document is obtainable

Author in charge of Dr. Soghra Khani

### What processes are involved for a request to access data/document

She/He must first send an email to the author of the article and submit her request, and if the author and the

research team deem it appropriate, the documents and files will be provided in a short time

**Comments**

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